

Appl. No. : 10/633,404
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AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method for ~~maintaining calibration of~~ calibrating a substantially continuous analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, comprising one or more reference data points;

providing at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data;

~~forming a calibration set including said at least one matching data pair;~~

creating a conversion function based on said ~~calibration set~~ at least one matched data pair;

~~converting sensor data into calibrated data using said conversion function;~~

~~subsequently obtaining one or more additional reference data points and creating one or more new matched data pairs;~~

~~evaluating said calibration set when said new matched data pair is created~~ at least one matched data pair, wherein evaluating said calibration set includes including at least one of 1) ensuring said at least one matched data pair ~~pairs in said calibration set span is within~~ a predetermined time range, 2) ensuring said at least one matched data pair is ~~pairs in said calibration set are~~ no older than a predetermined value, 3) ensuring said ~~calibration set has~~ said at least one matched data pair is substantially distributed with additional matched data pairs, if present, between high and low matched data pairs over ~~said a~~ predetermined time range, and 4) ~~allowing~~ ensuring said at least one matched data pairs only pair is within a predetermined range of analyte values, wherein the step of evaluating said at least one matched data pair further comprises at least one of evaluating a rate of change of the analyte concentration, evaluating a congruence of respective sensor and reference data in a matched data pair, and evaluating physiological changes; and

subsequently modifying said ~~calibration set~~ conversion function if such modification is required by said evaluation.

2. (Canceled)
3. (Currently amended) The method of claim 1, wherein the step of evaluating ~~said calibration set~~ comprises evaluating ~~said new~~ an initial matched data pair.
4. (Currently amended) The method of claim 1, wherein the step of evaluating ~~said calibration set includes~~ comprises evaluating ~~all of the matched data pairs in said calibration set and said new matched data pair~~ at least one subsequently received matched data pair.
5. (Currently amended) The method of claim 1, wherein the step of evaluating ~~said calibration set includes~~ comprises evaluating ~~combinations of matched data pairs from the calibration set and said new matched data pair~~ a plurality of matched data pairs.
6. (Currently amended) The method of claim 1, wherein the step of receiving sensor data comprises receiving a data stream from ~~a long term~~ an implantable analyte sensor.
7. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving a data stream that has been algorithmically smoothed.
8. (Original) The method of claim 1, wherein the step of receiving sensor data stream comprises algorithmically smoothing said data stream.
9. (Withdrawn) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a wireless connection.
10. (Original) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a wireless connection.
11. (Original) The method of claim 1, wherein the step of receiving reference data from a reference analyte monitor comprises receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.
12. (Original) The method of claim 1, wherein the reference analyte monitor comprises self-monitoring of blood analyte.
13. (Original) The method of claim 1, wherein the step of creating a conversion function comprises linear regression.
14. (Withdrawn) The method of claim 1, wherein the step of creating a conversion function comprises non-linear regression.

15. (Currently amended) The method of claim 1, wherein the step of ~~forming a calibration set comprises including in said calibration set~~ creating a conversion function is based on between one matched data pair and six matched data pairs.

16. (Currently amended) The method of claim 1, wherein the step of ~~forming a calibration set comprises including~~ creating a conversion function is based on at least two matched data pairs.

17. (Canceled)

18. (Currently amended) ~~The method of claim 17~~ A method for calibrating a substantially continuous analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, comprising one or more reference data points;

providing at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data;

forming a calibration set including said at least one matching data pair;

creating a conversion function based on said calibration set;

converting sensor data into calibrated data using said conversion function;

subsequently obtaining one or more additional reference data points and creating one or more new matched data pair[s];

evaluating said calibration set when said new matched data pair is created, wherein evaluating said calibration set includes at least one of 1) ensuring matched data pair[s] in said calibration set span a predetermined time range, 2) ensuring matched data pair[s] in said calibration set are no older than a predetermined value, 3) ensuring said calibration set has substantially distributed high and low matched data pair[s] over said predetermined time range, and 4) allowing matched data pair[s] only within a predetermined range of analyte values; and

subsequently modifying said calibration set if such modification is required by said evaluation, wherein the step of forming a calibration set further comprises determining a value for n, where n is greater than one and represents the number of

matched data pair[s] in the calibration set, wherein the step of determining a value for n is determined as a function of the frequency of the received reference data points and signal strength over time.

19. (Currently amended) The method of claim 1, further comprising determining a set of ~~matching~~ matched data pairs ~~from said evaluation of said calibration set and re-forming a calibration set responsive to the evaluating step.~~

20. (Currently amended) The method of claim 19, further comprising repeating the step of ~~re-creating~~ creating said conversion function using said ~~re-formed calibration set of~~ matched data pairs.

21. (Currently amended) The method of claim 1 or 20, further comprising converting sensor data into calibrated data using said ~~re-created~~ conversion function.

22. (Currently amended) A system for ~~maintaining calibration of~~ calibrating a substantially continuous analyte sensor, the system comprising:

means for receiving a data stream from an analyte sensor, a plurality of time-spaced sensor data points;

means for receiving reference data from a reference analyte monitor, comprising one or more reference data points;

means for providing one or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

~~means for forming a calibration set comprising at least one matched data pair;~~

means for creating a conversion function based on said ~~calibration set~~ one or more matched data pairs;

~~means for converting sensor data into calibrated data using said conversion function;~~

~~subsequently obtaining one or more additional reference data points and creating one or more new matched data pairs;~~

means for evaluating said ~~calibration set when said new matched data pair is created, wherein evaluating said calibration set includes~~ one or more matched data pairs including at least one of 1) ensuring one or more matched data pairs ~~in said calibration set span~~ is within a predetermined time range, 2) ensuring one or more matched data pairs

~~in said calibration set~~ are no older than a predetermined value, 3) ensuring said ~~calibration set has one or more matched data pairs have~~ substantially distributed high and low matched data pairs over ~~said a~~ predetermined time range, and 4) ~~allowing~~ ensuring ~~said one or more matched data pairs only are~~ within a predetermined range of analyte values, wherein said means for evaluating said one or more matched data pairs further comprises at least one means for evaluating a rate of change of the analyte concentration, means for evaluating a congruence of respective sensor and reference data in matched data pairs, and means for evaluating physiological changes; and

means for modifying said ~~calibration set~~ conversion function if such modification is required by said ~~evaluation~~ means for evaluating.

23. (Canceled)

24. (Currently amended) The system of claim 22, wherein said means for evaluating ~~said calibration set~~ comprises means for evaluating said one or more new initial matched data pairs.

25. (Currently amended) The system of claim 22, wherein said means for evaluating ~~said calibration set includes~~ comprises means for evaluating ~~all of the matched data pairs in said calibration set and~~ said one or more new subsequently received matched data pairs.

26. (Currently amended) The system of claim 22, wherein said means for evaluating ~~said calibration set includes~~ comprises means for evaluating ~~combinations of matched data pairs from the calibration set and said one or more new matched data pair~~ a plurality of matched data pairs.

27. (Currently amended) The system of claim 22, wherein said means for receiving sensor data comprises means for receiving sensor data from ~~a long-term~~ an implantable analyte sensor.

28. (Original) The system of claim 22, wherein said means for receiving sensor data comprises means for receiving sensor data that has been algorithmically smoothed.

29. (Original) The system of claim 22, wherein said means for receiving sensor data comprises means for algorithmically smoothing said receiving sensor data.

30. (Withdrawn) The system of claim 22, wherein said means for receiving reference data comprises means for downloading reference data via a cabled connection.

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31. (Original) The system of claim 22, wherein said means for receiving reference data comprises means for downloading reference data via a wireless connection.

32. (Original) The system of claim 22, wherein said means for receiving reference data from a reference analyte monitor comprises means for receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

33. (Original) The system of claim 22, wherein said means for receiving reference data comprises means for receiving from a self-monitoring of blood analyte.

34. (Original) The system of claim 22, wherein said means for creating a conversion function comprises means for performing linear regression.

35. (Withdrawn) The system of claim 22, wherein said means for creating a conversion function comprises means for performing non-linear regression.

36. (Currently amended) The system of claim 22, wherein said means for ~~forming a calibration set~~ comprises ~~including in said calibration set~~ creating a conversion function is based on between one matched data pair and six matched data pairs.

37. (Currently amended) The system of claim ~~22~~ 26, wherein said means for ~~forming a calibration set~~ comprises ~~including in said calibration set~~ creating a conversion function is based on at least two matched data pairs.

38. (Canceled)

39. (Currently amended) ~~The system of claim 38,~~ A system for calibrating a substantially continuous analyte sensor, the system comprising:

means for receiving a data stream from an analyte sensor, a plurality of time-spaced sensor data points;

means for receiving reference data from a reference analyte monitor, comprising one or more reference data points;

means for providing one or more matched data pair[s] by matching reference analyte data to substantially time corresponding sensor data;

means for forming a calibration set comprising at least one matched data pair;

means for creating a conversion function based on said calibration set;

means for converting sensor data into calibrated data using said conversion function;

subsequently obtaining one or more additional reference data points and creating one or more new matched data pair[s];

means for evaluating said calibration set when said new matched data pair is created, wherein evaluating said calibration set includes at least one of 1) ensuring matched data pair[s] in said calibration set span a predetermined time range, 2) ensuring matched data pair[s] in said calibration set are no older than a predetermined value, 3) ensuring said calibration set has substantially distributed high and low matched data pair[s] over said predetermined time range, and 4) allowing matched data pair[s] only within a predetermined range of analyte values; and

means for modifying said calibration set if such modification is required by said evaluation wherein the means for forming a calibration set further comprises determining a value for n, where n is greater than one and represents the number of matched data pair[s] in the calibration set, and wherein the means for determining a value for n is determined as a function of the frequency of the received reference data points and signal strength over time.

40. (Currently amended) The system of claim 22, further comprising means for determining a set of ~~matching~~ matched data pairs from said evaluation ~~of said calibration set and re-forming a calibration set.~~

41. (Currently amended) The system of claim 40, further comprising said means for repeating the set step of creating said a conversion function using said ~~re-formed calibration set of matched data pairs.~~

42. (Currently amended) The system of claim 41, further comprising means for converting sensor data into calibrated data using said ~~re-created~~ conversion function.

43. (Currently amended) A computer system for ~~maintaining calibration of~~ calibrating a substantially continuous analyte sensor, the computer system comprising:

a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference data receiving module that receives reference data from a reference analyte monitor, including two or more reference data points;

a data matching module that forms one or more matched data pair[s] by matching reference data to substantially time corresponding sensor data;

~~a calibration set module that forms a calibration set comprising at least one matched data pair;~~

a conversion function module that creates a conversion function using said calibration set one or more matched data pairs;

~~a sensor data transformation module that converts sensor data into calibrated data using said conversion function; and~~

a calibration evaluation module that evaluates one or more matched data pair[s] said calibration set when said new matched data pair is provided, wherein evaluating said calibration set one or more matched data pairs includes at least one of 1) ensuring said one or more matched data pairs in said calibration set span is within a predetermined time period, 2) ensuring said one or more matched data pairs in said calibration set are is no older than a predetermined value, 3) ensuring said calibration set has one or more matched data pairs have substantially distributed high and low matched data pairs over a predetermined time range, and 4) allowing ensuring said one or more matched data pairs only is within a predetermined range of analyte values, wherein said evaluation calibration module further evaluates at least one of a rate of change of the analyte concentration, a congruence of respective sensor and reference data in matched data pairs, and physiological changes, and

wherein said conversion function module is programmed to re-create said conversion function ~~of~~ if such modification is required by said calibration evaluation module.

44. (Canceled)

45. (Currently amended) The computer system of claim 43, wherein said evaluation calibration evaluation module evaluates said new an initial one or more matched data pair pairs.

46. (Currently amended) The computer system of claim 43, wherein said evaluation calibration evaluation module evaluates all of the matched data pairs in said calibration set and said new matched data pair one or more subsequently received matched data pairs.

47. (Currently amended) The computer system of claim 43, wherein said evaluation calibration evaluation module evaluates combinations of matched data pairs from the calibration set and said new matched data pair a plurality of matched data pairs.

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48. (Currently amended) The computer system of claim 43, wherein said sensor data receiving module receives said data stream from ~~a long-term~~ an implantable analyte sensor.

49. (Original) The computer system of claim 43, wherein said sensor data receiving module receives an algorithmically smoothed data stream.

50. (Original) The computer system of claim 43, wherein said sensor data receiving module comprises programming to smooth said data stream.

51. (Withdrawn) The computer system of claim 43, wherein said reference data receiving module downloads reference data via a cabled connection.

52. (Original) The computer system of claim 43, wherein said reference data receiving module downloads reference data via a wireless connection.

53. (Original) The computer system of claim 43, wherein said reference data receiving module receives within a receiver internal communication from a reference analyte monitor integral with said receiver.

54. (Original) The computer system of claim 43, wherein said reference data receiving module receives reference data from a self-monitoring of blood analyte.

55. (Original) The computer system of claim 43, wherein said conversion function module comprises programming that performs linear regression.

56. (Withdrawn) The computer system of claim 43, wherein said conversion function module comprises programming that performs non-linear regression.

57. (Currently amended) The computer system of claim 43 ~~47~~, wherein said ~~calibration set module includes in said calibration set~~ conversion function module creates the conversion function based on between one matched data pair and six matched data pairs.

58. (Currently amended) The computer system of claim 43 ~~47~~, wherein said ~~calibration set module includes in said calibration set~~ conversion function module creates the conversion function based on at least two matched data pairs.

59. (Canceled)

60. (Currently amended) ~~The computer system of claim 59~~ A computer system for calibrating a substantially continuous analyte sensor, the computer system comprising:

a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference data receiving module that receives reference data from a reference analyte monitor, including two or more reference data points;

a data matching module that forms one or more matched data pair[s] by matching reference data to substantially time corresponding sensor data;

a calibration set module that forms a calibration set comprising at least one matched data pair;

a conversion function module that creates a conversion function using said calibration set;

a sensor data transformation module that converts sensor data into calibrated data using said conversion function; and

a calibration evaluation module that evaluates said calibration set when said new matched data pair is provided, wherein evaluating said calibration set includes at least one of 1) ensuring matched data pair[s] in said calibration set span a predetermined time period, 2) ensuring matched data pair[s] in said calibration set are no older than a predetermined value, 3) ensuring said calibration set has substantially distributed high and low matched data pair[s] over a predetermined time range, and 4) allowing matched data pair[s] only within a predetermined range of analyte values,

wherein said conversion function module is programmed to re-create said conversion function of such modification is required by said calibration evaluation module, wherein said programming for determining a value for n determines n as a function of the frequency of the received reference data points and signal strength over time, and wherein the calibration set module further comprises programming for determining a value for n, wherein n is greater than one and represents the number of matched data pairs in the calibration set.

61. (Currently amended) The computer system of claim 43, wherein data matching module further comprises programming to ~~re-form said calibration~~ form a set of matched data pairs based on responsive to said calibration evaluation.

62. (Currently amended) The computer system of claim 61, wherein said conversion function module further comprises programming to ~~re-create said~~ create a conversion function based on said ~~re-formed calibration set of matched data pairs.~~

63. (Currently amended) The computer system of claim 43 or 62, further comprising a sensor data transformation module ~~further~~ comprising programming for converting sensor data into calibrated data using said ~~re-created~~ conversion function.

64. (Currently amended) A method for ~~maintaining calibration of~~ calibrating a glucose sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including one or more reference data points;

providing at least one matched data pair by matching reference analyte data to substantially time corresponding sensor data;

~~forming a calibration set including said at least one matching data pairs;~~

creating a conversion function based on ~~said calibration set~~ at least one matched data pair; and

~~subsequently obtaining one or more additional reference data points and creating one or more new matched data pairs; and~~

~~evaluating said calibration set when said new matched data pair is created~~ at least one of said matched data pairs, wherein evaluating said ~~calibration set~~ includes comprises at least one of 1) ~~ensuring matched data pairs in said calibration set span a predetermined time range,~~ 2) ~~ensuring matched data pairs in said calibration set are no older than a predetermined value,~~ 3) ~~ensuring said calibration set has substantially distributed high and low matched data pairs over said predetermined time range,~~ and 4) ~~allowing matched data pairs only within a predetermined range of analyte values~~ evaluating a rate of change of the analyte concentration, evaluating a congruence of respective sensor and reference data in a matched data pair, and evaluating physiological changes.

65. (Currently amended) A computer system for ~~maintaining calibration of~~ calibrating a glucose sensor, the computer system comprising:

a sensor data module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference input module that receives reference data from a reference analyte monitor, the reference data comprising one or more reference data points;

a processor module that forms one or more matched data pairs by matching reference data to substantially time corresponding sensor data and subsequently forms a calibration set comprising said one or more matched data pairs; and

a calibration evaluation module that evaluates ~~said calibration set when said new matched data pair is provided~~ one or more matched data pairs, wherein said evaluation calibration module evaluates at least one of a rate of change of the analyte concentration, a congruence of respective sensor and reference data in matched data pairs, and physiological changes, ~~wherein evaluating said calibration set includes at least one of 1) ensuring matched data pairs in said calibration set span a predetermined time period, 2) ensuring matched data pairs in said calibration set are no older than a predetermined value, 3) ensuring said calibration set has substantially distributed high and low matched data pairs over a predetermined time range, and 4) allowing matched data pairs only within a predetermined range of analyte values,~~
~~wherein said conversion function module is programmed to re-create said conversion function of such modification is required by said calibration evaluation module.~~

66. (New) The method of claim 64, wherein the step of matching reference analyte data to substantially time corresponding sensor data comprises determining a best matched pair at least in part by comparing a reference data point against a plurality of individual sensor values over a predetermined time period.

67. (New) The method of claim 64, wherein the step of matching reference analyte data to substantially time corresponding sensor data is at least in part based on a time lag of at least about 5 minutes in the sensor data as compared to the reference data.

68. (New) The method of claim 64, wherein the step of matching reference analyte data to substantially time corresponding sensor data comprises matching a reference data point with an average of a plurality of sensor data points over a predetermined time period.

69. (New) The method of claim 64, wherein the step of evaluating at least one of said matched data pairs further comprises ensuring said at least one of said matched data pairs is within a predetermined range of analyte values.

70. (New) The method of claim 64, wherein the step of evaluating at least one of said matched data pairs further comprises evaluating a clinical acceptability of a disparity between the reference data point and time corresponding sensor data point of said at least one of said matched data pairs.

71. (New) The method of claim 64, wherein the step of evaluating at least one of said matched data pairs further comprises ensuring at least one of said matched data pairs is within a predetermined time range.

72. (New) The method of claim 64, wherein the step of evaluating at least one of said matched data pairs further comprises ensuring at least one of said matched data pair is no older than a predetermined value.

73. (New) The method of claim 64, wherein said at least one of said matched data pairs comprise two or more matched data pairs, and wherein the step of evaluating further comprises ensuring that the two or more matched pairs have substantially distributed values

74. (New) The system of claim 65, wherein the processor module is configured match reference data to substantially time corresponding sensor data at least in part by evaluating a best matched pair by comparing a reference data point against a plurality of individual sensor values over a predetermined time period.

75. (New) The system of claim 65, wherein the processor module is configured match reference data to substantially time corresponding sensor data at least in part based on a time lag of at least about 5 minutes in the sensor data as compared to the reference data.

76. (New) The system of claim 65, wherein the processor module is configured match reference data to substantially time corresponding sensor data is configured to match a reference data point with an average of a plurality of sensor data points over a predetermined time period.

77. (New) The system of claim 65, wherein the calibration evaluation module is further configured to ensure one or more matched data pairs is within a predetermined range of analyte values.

78. (New) The system of claim 65, wherein the calibration evaluation module is further configured to evaluate a clinical acceptability of a disparity between the reference data point and time corresponding sensor data point of one or more matched data pairs.

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79. (New) The system of claim 65, wherein the step of evaluating at least one of said matched data pairs further comprises ensuring said at least one of said matched data pairs is within a predetermined time range.

80. (New) The system of claim 65, wherein the calibration evaluation module is further configured to ensure one or more matched data pairs is no older than a predetermined value.

81. (New) The system of claim 65, wherein said one or more matched data pairs comprise two or more matched data pairs, and wherein the calibration evaluation module is further configured to ensure that the two or more matched data pairs have substantially distributed values.